

REMARKS

I. Claim Status

Reconsideration of the present application is respectfully requested. Claims 1, 3-9, 11, 12, 13, 15, 31, 32, 35 and 36 are pending. Claims 2, 10, 14, 16-30, 33 and 34 are canceled without prejudice. Claims 1 and 11 are amended. Claims 35 and 36 are new. Support for these amendments can be found throughout the specification and claims as originally filed, for example, at page 5, paragraph [0038] and pages 14-15, paragraphs [0096]-[00101] of the published application; and claims 2, 10, 11, 16, and 17 as originally filed. No new matter is added by way of this amendment.

II. Claim Objection

The Examiner has objected to claim 11 as being of improper dependent form for failing to further limit the subject matter of a previous claim. Without conceding to the Examiner's contention, and solely to further prosecution of the present application, Applicants have amended claim 11 to recite "the anti-irritant composition of Claim 1, further comprising an antimicrobial compound selected from the group consisting of . . ." thus placing the claim in proper dependent form. Withdrawal of the claim objection is respectfully requested.

III. Rejections Under 35 U.S.C. § 112

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-9, 11-13, 15, 17 and 31-34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner contends that independent claims 1 and 33 recite an anti-irritant composition comprising one or more antimicrobial compounds selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, iodopropynylbutyl carbamate, and combinations thereof at a concentration of between 0.05% - 4% (weight/weight). According to the Examiner, when two or more antimicrobial compounds are present, it is unclear whether the claimed concentration refers to the individual antimicrobial agents, or the combined amount of the agents. Applicants have amended the claims to recite that the claimed

concentration refers to the concentration of individual antimicrobial agents (*see, e.g.*, Claim 10 as originally filed). Applicants respectfully request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-9, 11-13, 15, 17 and 31-34 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims are directed to compositions that exhibit a synergistic preservative effect against bacteria. According to the Examiner, the specification lacks support for specific compositions that exhibit such an effect. The Examiner contends that Table 10 of the application (*see*, page 48 of the specification), discloses specific formulations of gel compositions that exhibited synergistic preservative effects against *S. aureus*. However, the Examiner states that the compositions encompassed by the claims are broader in scope than those of Table 10, and the application provides no support that such compositions can achieve a synergistic preservative effect against *S. aureus* or other bacteria.

Applicants respectfully disagree. Example 10 of the application (*see*, the published application at paragraphs [0096]-[0101]) describes the discovery that inicroquat synergistically potentiates the antimicrobial effect of chlorhexidine gluconate and benzalkonium chloride. Such an effect was not previously appreciated by the prior art:

[w]hat was not previously appreciated in the art, however, was that the addition of inicroquat significantly potentiates the preservative effects of chlorhexidine gluconate and benzalkonium chloride.

See, page 14, paragraph [0096] of the published application. Furthermore, Example 10 discloses that the addition of zinc salts into formulations comprising inicroquat, chlorhexidine gluconate and benzalkonium chloride does not reduce the synergistic antimicrobial effect of the three ingredients. *See*, page 14, paragraph [0099] of the published application.

Although Example 10 discloses compositions of specific formulations, an artisan of ordinary skill would understand that the synergistic antimicrobial effect was an effect achieved by combining inicroquat, chlorhexidine gluconate and benzalkonium chloride together, as formulations that did not include any of these ingredients had no antimicrobial effect (*see*, page 14, Tables 10 and 11, disclosing that Gel #1 had no antimicrobial effect). Thus, the skilled artisan would understand that other ingredients may be included in a composition comprising

incroquat, chlorhexidine gluconate and benzalkonium chloride while still maintaining an antimicrobially synergistic effect. Applicants also note that in addition to the formulations described by Example 10, the present application discloses other formulations that include incroquat, chlorhexidine gluconate and benzalkonium chloride along with other ingredients. When the antimicrobial effect of any of these formations was tested, an antimicrobial effect against up to six different microbes was achieved. *See*, pages 10-12, paragraphs [0083]-[0085] and Tables 7-8 (disclosing that formulating incroquat, chlorhexidine gluconate and benzalkonium chloride with other ingredients, or ranges (w/w) of ingredients, than those disclosed in Example 10 had antimicrobial effects against *S. aureus*, *S. epidermis*, *S. aureus* (methicillin resistant), *K. pneumoniae*, *E. coli*, and/or *C. albicans*.) Thus, the skilled artisan would understand that the compositions encompassed by the specification are broader than those specifically disclosed by Example 10. Applicants submit that such disclosure is sufficient to support the genus of compounds encompassed by the amended claims:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

See, Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d at 956, 966 (Fed.Cir.2002); and M.P.E.P. § 2163.05. Thus, because of Applicants discovery that combining incroquat, chlorhexidine gluconate and benzalkonium chloride together produces a synergistic antimicrobial effect, and further, the application's contemplation of a broad scope of formulations including incroquat, chlorhexidine gluconate and benzalkonium chloride, Applicants submit that the specification supports the scope of the amended claims. Applicants respectfully request that the rejection be withdrawn.

IV. Rejections Under 35 U.S.C. § 103(a)

U.S. Patent No. 5,985,918 to Modak et al. and U.S. Patent No. 5,965,610 to Modak et al. in view of U.S. Publication No. 2002/0098159 to Wei et al.

Claims 1-9, 11-13, 15, 17 and 31-34 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,985,918 to Modak et al. (hereafter “the ‘918 patent”) and U.S. Patent No. 5,965,610 to Modak et al. (hereafter “the ‘610 patent”), in view of U.S. Publication No. 2002/0098159 to Wei et al. (hereafter “Wei”). The Examiner maintains that the ‘918 patent describes anti-irritant topical formulations comprising water, emollients and two or more organic salts of zinc in a concentration of between 0.1-15%. The Examiner further maintains that the ‘610 patent describes an anti-irritant gel comprising 1-10% zinc gluconate, 1-10% incoquat behenyl TMS, water, emollients and 0.4-4% of an antimicrobial agent such as chlorhexidine gluconate. The Examiner further states that Wei describes topical cream compositions comprising gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emollients and antimicrobial agents such as benzalkonium chloride, among other ingredients. According to the Examiner, the composition defined by the three references comprises all the elements of the pending claims, rendering the claims obvious.

Applicants respectfully disagree. The claims as amended are not obvious over the cited references when considered separately or in combination. To support an assertion of obviousness, the Examiner must show that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.” M.P.E.P. § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

The claims as amended recite an anti-irritant composition comprising, among other things, two or more water-soluble, organic salts of zinc selected from the group consisting of zinc acetate, zinc butyrate, zinc citrate, zinc gluconate, zinc glycerate, zinc glycolate, zinc formate, zinc lactate, zinc picolinate, zinc propionate, zinc tartrate and zinc undecylenate. None of the ‘918 patent, the ‘610 patent, or Wei suggest or describe an anti-irritant composition comprising two or more water-soluble, organic salts of zinc, as encompassed by the amended claims.

Applicants submit that although the '918 patent is directed to anti-irritant compositions that utilize organic salts of zinc (*see, e.g.,* the '918 patent at Co. 1, lines 53-60 which discloses that the organic zinc salts include zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laureate, zinc stearate, zinc caproate, zinc gallate, zinc lactate, zinc myristate, zinc palmitate, and zinc propionate), the patent only contemplates compositions comprising two or more zinc salts when zinc salicylate is also present in the composition, or when the two zinc salts are zinc stearate and zinc acetate. With regard to the inclusion of two or more zinc salts in a single compositions, the '918 patent discloses that zinc salicylate can be combined with one or more organic zinc salt:

In particular embodiments, the cream may comprise 0.1-1 percent by weight of zinc salicylate, wherein one or more other organic zinc salts may optionally be present.

See, the '918 patent at Col. 2, lines 29-31. Furthermore, the patent also discloses compositions comprising zinc stearate and zinc acetate. *See*, the '918 patent at Col. 3, Table A. As previously discussed, the claims as amended encompass a composition that includes two or more water-soluble, organic salts of zinc selected from a defined group of water-soluble, organic zinc salts. Said group does not include zinc salicylate or zinc stearate. Thus, in view of the '918 patent, an artisan of ordinary skill would not have formulated an anti-irritant composition with two or more water-soluble, organic salts of zinc as recited by the amended claims.

Additionally, Applicants note that the zinc salts described by the '918 patent are characterized as being not-readily soluble. *See*, the '918 patent at Col. 1, lines 61-67. The disclosure is in contrast to pending claim 1 in the present application, which recites a composition comprising two or more water-soluble, organic salts of zinc. Such disclosure by the '918 patent is further evidence of the lack of guidance the reference provides the skilled artisan in practicing the claimed invention.

Applicants also submit that the '610 patent is directed to an anti-irritant gel comprising water, emollients, antimicrobial agents (*e.g.,* chlorhexidine gluconate), and a cationic substance, such as a soluble zinc salt (*e.g.,* zinc gluconate). However, although the '610 patent discloses that a soluble zinc salt may be included in the disclosed composition, the reference does not disclose or suggest that such composition can include two or more water-soluble, organic salts of zinc, as encompassed by the claims. *See*, the '610 patent at Col. 7, lines 4-10. Thus, the

combined disclosure of both the '610 patent and the '918 patent does not disclose that an anti-irritant composition can be formulated with two or more water-soluble, organic zinc salts as recited by the amended claims.

With regard to Wei, the Examiner relies on the reference for its disclosure of compositions comprising gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emollients and antimicrobial agents such as benzalkonium chloride, among other ingredients. Applicants note that the reference is silent with regard to the inclusion of water-soluble, organic salts of zinc in a topical antimicrobial composition. As such, combining the disclosure of Wei with those of the '610 patent and the '918 patent does not rectify the two patents' failure in disclosing the claimed invention.

Thus, because the combined teaching of the cited references does not disclose all the elements of the claimed invention, and further, because the combined disclosure provides an artisan of ordinary skill with no guidance in practicing the claimed invention, the claims as amended are not obvious over the cited references. Applicants respectfully request that the rejection be withdrawn. All of Applicants' amendments and arguments are made without prejudice or disclaimer. Applicants reserve the right to present further arguments and distinctions in an Appeal, if appropriate. Moreover, Applicants' silence in the face of any additional statements made by the Examiner should not be interpreted as acquiescence. Instead, Applicants believe that the arguments made herein are sufficient to overcome the Examiner's rejections or render the Examiner's rejections moot.

V. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no fees in addition to the fee associated with the Petition to extend time are due at this time. However, if any other fees are required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,

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